Citation:

Leidy HL, Carnell NS, Mattes RD, Campbell WW. Higher protein intake preserves lean mass and satiety with weight loss in pre-obese and obese women. *Obesity (Silver Spring)* 2007;15(2):421-429.

PubMed ID: 17299116

Study Design:

Randomized Clinical Trial

Class:

A - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

The primary purpose of this study was to investigate the effects of a higher-protein versus a normal-protein 12-week energy restricted diet on body weight, body composition, appetite, mood and markers of cardiovascular and kidney functions. The secondary purpose of this study was to investigate whether overweight status (overweight versus obese) affects energy restriction-induced changes in the above parameters.

Inclusion Criteria:

Inclusion criteria included the following:

- women aged 21 years or older;
- body mass index (BMI) between 25 and 37 kg/m^2;
- no dieting or weight loss >4.5 kg within the previous 6 months;
- non-smoking;
- stable activity pattern within the previous 3 months;
- clinically normal blood profiles (specifically, normal liver and kidney functions and normal blood glucose concentrations); and
- non-diabetic.

Exclusion Criteria:

Exclusion criteria included the following:

- smoking;
- abnormal blood profiles for liver and kidney functions;
- abnormal blood glucose concentrations; and
- presence of diabetes.

Description of Study Protocol:

Recruitment

Participants were recruited from newspaper advertisements and posted flyers.

Design: Randomized clinical trial

- This study was a 12-week feeding study.
- Participants were randomly assigned to one of two groups and consumed either a higher-protein (HP) diet (30% of total calories derived from protein) or normal-protein (NP) diet (18% of total calories derived from protein).
- Participants were retrospectively subgrouped according to body mass index (BMI), either pre-obese (POB) (25.0-29.9 kg/m^2) or obese (OB) (30.0-37.0 kg/m^2). This resulted in the following groups: HP-POB (N=9), NP-POB (N=11), HP-OB (N=12), and NP-OB (n=14).

Blinding used (if applicable): implied with measures

Intervention

- Participants consumed one of either two diets for 12 weeks.
- The HP diet consisted of 30% of calories from protein, 45% of calories from carbohydrate and 25% of calories from fat.
- The NP diet consisted of 18% of calories from protein, 57% of calories from carbohydrate and 25% of calories from fat.
- Both groups received a multivitamin/mineral supplement and 2 calcium citrate tablets (400 mg calcium/tablet).

Statistical Analysis

- Student's *t*-test was used to compare participants per protein intake.
- Repeated-measures ANOVA was used to examine the main effects of time, protein intake and/or BMI status.
- Post-hoc analyses were performed using Student's *t*-tests to detect differences within and between NP and HP groups.
- $P < 0.05$ was considered statistically significant. SPSS (Version 14.0; SPSS, Chicago, IL) was used to analyze data.

Data Collection Summary:

Timing of Measurements

Pre- and post-measurements included the following: body weight, body composition, appetite, mood, fasting blood samples (total cholesterol, HDL-cholesterol, triacylglycerol, glucose and creatinine), glomerular filtration rate (GFR), blood pressure and blood-urea nitrogen (BUN).

Dependent Variables

- Body weight: measured twice weekly using an electronic platform scale (ESL200L; Mettler, Toledo, OH)
- Body composition: whole and regional body composition measured at baseline and study completion using DXA (GE LUNAR Prodigy with EnCORE software version 5.6, Madison,

WI)
- Appetite and mood state: measured using questionnaires every waking hour for 3 nonconsecutive days during both pre- and post-intervention using a 100-point rating scale on a personal digital assistant (Palm-Pilot M100; Palm Computing, Sunnyvale, CA)
- Cardiovascular, metabolic and kidney disease risk factors (all were measured at baseline and week 12):
    - fasting blood samples taken from antecubital vein to measure total cholesterol, HDL-cholesterol, triacylglycerol, glucose and creatinine using photometric assays (Chemistry Immuno Analyzer AU5700; Olympus, Center Valley, PA, performed by MidAmerica Clinical Laboratories in Indianapolis, IN);
    - LDL-cholesterol was measured using the following equation: LDL-C=total cholesterol - HDL-C - triacylglycerol/5;
    - kidney function was measured using glomerular filtration rate (GFR) based on the Modification of Diet in Renal Disease equation;
    - blood pressure measured by the same research technician using a sphygmomanometer; and
    - total protein intake using fasting blood samples to measure blood urea nitrogen (BUN) via a photometric assay (Chemical Immuno Analyzer AU5700; Olympus).

Independent Variables

Participants followed one of the two following diets:

- higher protein (HP) diet: consisted of 30% protein, 45% carbohydrate and 25% fat; or
- normal protein (NP) diet: consisted of 18% protein, 57% carbohydrate and 25% fat.

Control Variables

- All participants were given a multivitamin/mineral supplement and 2 calcium citrate supplements (400 mg calcium/tablet).

Description of Actual Data Sample:

Initial N: 54

Attrition (final N): 46 (8 dropped out at week 1; 6 due to scheduling, 2 due to health issues)

Age: 50 ± 2 years

Ethnicity: Not given

Other relevant demographics

Anthropometrics: Average BMI = 30.6 ± 0.5 kg/m^2. There were no differences in age, height, weight, BMI, or body composition between the groups at baseline.

Location: West Lafayette, Indiana, USA

Summary of Results:

Key Findings

- Regardless of diet group, actual total energy, protein, carbohydrate and fat intakes were slightly lower than prescribed at end of 12 weeks. However, the HP group consumed significantly more protein at the end of the study (29.5 ± 0.1% of total intake from protein per day) as compared to the NP group (18.2 ± 0.1% of total intake from protein) ($P < 0.001$).
- The HP diet led to significant increase in BUN (+1.5 ± 0.8 mg/dL) as compared to those following the NP diet (-2.3 ± 0.5 mg/dL).
- A gradual loss of body weight was observed in all participants, regardless of protein intake.
- Weight loss was not different between the two dietary intervention groups.
- All groups lost significant amounts of fat mass ($P < 0.001$) and lean body mass ($P < 0.001$) by study end.
- The HP group had greater preservation of lean body mass compared with the NP group ($P < 0.05$).
- No significant differences in appetite occurred between groups from pre- to post-intervention. Average meal-related feelings of fullness were reduced after 12-week energy restriction ($P < 0.05$). However, reduction in post-prandial feelings of satisfaction were less pronounced in HP (10%) versus NP (27%) ($P < 0.005$).
- No significant differences occurred in glucose, creatinine, GFR, HDL-cholesterol, LDL-cholesterol and triacylglycerol responses between groups at post-intervention.
- Systolic and diastolic blood pressure decreased after energy restriction with no differences in responses between groups ($P < 0.05$).

Author Conclusion:

In conclusion, the consumption of a HP energy-restricted diet led to better preservation of lean body mass while losing body weight and body fat along with a smaller reduction in satiety and increased global pleasure. Furthermore, the preservation of lean tissue seems to be additive for those women who are overweight (pre-obese) consuming a HP diet.

Reviewer Comments:

Small numbers of subjects in retrospective analysis.

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions

1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions		
1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	Yes
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes

4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	Yes
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	Yes
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	No
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	Yes
6.6.	Were extra or unplanned treatments described?	No
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes

7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	No
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	Yes
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	No
10.	**Is bias due to study's funding or sponsorship unlikely?**	Yes
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes